Evidence To Support Using The Precautionary Principal In PUC Public Policy In Consideration Of The Uncertainy Of Safety From Exposure To Electromagnetic Radiation

- 1A Qualified, peer-reviewed and published research scientists in the field of EMF that have looked at the existing body of evidence regarding the biological effects of exposure to EMF and concluded that a Precautionary Principal should be applied:
 - 1. Dämvik M, Johansson O. Health risk assessment of electromagnetic fields: a conflict between the precautionary principle and environmental medicine methodology. Rev Environ Health. 2010 Oct-Dec;25(4):325-33. http://www.ncbi.nlm.nih.gov/pubmed/21268445 Abstract: The purpose of the precautionary principle is that legal requirements are to be made to safeguard against the possible health risks that have not yet been scientifically established. That a risk is not established cannot, therefore, be used as an excuse for not applying the principle. Yet, that rationale is exactly what is happening in the case of the possible health risks from exposure to electromagnetic fields (EMF). The scientists, representing both the World Health Organization and the European Commission, do not have at all the precautionary principle in mind when they report on health risks. Their starting point is instead to determine whether new research findings have been scientifically established and thus cannot be the basis for an amendment to the existing exposure limits. Uncertain indications of risk are ignored or played down. This approach is in conflict with European Union (EU) law, which requires that the degree of scientific uncertainty should be presented correctly. A thorough examination of the state of research shows many serious indications of possible health risks from exposure very far below existing limits for EMF. Case law, for other types of exposure, also shows that the precautionary principle can be applied on the basis of weaker evidence than that. Our investigation shows that the precautionary principle is not being used for its intended purpose in relation to exposure to EMF. The reason for this position is that decision-makers are being misled by inaccurate risk assessments.
 - 2. Fragopoulou A, Grigoriev Y, Johansson O, Margaritis LH, Morgan L, Richter E, Sage C.. 2010. Scientific panel on electromagnetic field health risks: consensus points, recommendations, and rationales. Rev Environ Health. 2010 Oct-Dec;25(4):307-17. http://www.ncbi.nlm.nih.gov/pubmed/21268443 Abstract: In November, 2009, a scientific panel met in Seletun, Norway, for three days of intensive discussion on existing scientific evidence and public health implications of the unprecedented global exposures to artificial electromagnetic fields (EMF). EMF exposures (static to 300 GHz) result from the use of electric power and from wireless telecommunications technologies for voice and data transmission, energy, security, military and radar use in weather and transportation. The Scientific Panel recognizes that the body of evidence on EMF requires a new approach to protection of public health; the growth and development of the fetus, and of children; and argues for strong preventative actions. New, biologically-based public exposure standards are urgently needed to protect public health worldwide
 - 3. Grandjean P, Science For Precautionary Decision -Making. In: Late Lessons From Early Warnings: Science, Precaution, Innovation Volume II, Part E.26- More Or Less Precaution?. European Environment Agency Report No. 1/2013, Copenhagen, Denmark [Full copy filed in Docket] Excerpt (pg. 37): Misinterpretation may occur when results published in scientific journals are expressed in hedged language. For example, a study that fails to document with statistical significance the presence

of a hazard is often said to be negative, and the results may be misinterpreted as evidence that a hazard is absent. Such erroneous conclusions are inspired by science traditions, which demand meticulous and repeated examination before a hypothesis can be said to be substantiated. For prioritizing needs for action, research should instead focus on identifying the possible magnitude of potential hazards. Research is always affected by uncertainties and many of them can blur a real association between an environmental hazard and its adverse effects, thereby resulting in an underestimated risk. For prioritizing needs for action, research should instead focus on identifying the possible magnitude of potential hazards.

- 4. Guiliani, L. & Soffritti, M. eds.: Annex: 'Non thermal effects and mechanisms of interaction between EMF and living matter: a selected Summary' ICEMS, Ramazzini Institute, European J of Oncology, Library, Vol. 5, 2010. (Copy filed in Docket) Excerpt (pg. 15): The biological evidence concerning the non thermal effects of EMF (indications of head cancer, permeability of the brain/blood barrier (p. 319, 333); expression of shock proteins; genotoxic damage, neurological, and possibly reproductive effects), though still limited and controversial, is sufficient, on a precautionary basis, to justify biologically based and lower safety limits for the public.
- 5. Hardell L, Carlberg M, Gee D, *Mobile phone use and brain tumour risk: early warnings, early actions? In: Late lessons from early warnings: science, precaution, innovation Volume II, Part C.21*. European Environment Agency, Report No. 1/2013, Copenhagen, Denmark [Copy filed in Docket] Excerpt (pg. 31): The chapter points to mobile phone industry inertia in considering the various studies and taking the IARC carcinogenic classification into account and a failings from the media in providing the public with robust and consistent information on potential health risks. The IARC carcinogenic classification also appears not to have had any significant impact on governments' perceptions of their responsibilities to protect public health from this widespread source of radiation. The benefits of mobile telecommunications are many but such benefits need to be accompanied by consideration of the possibility of widespread harms. Precautionary actions now to reduce head exposures would limit the size and seriousness of any brain tumour risk that may exist. Reducing exposures may also help to reduce the other possible harms that are not considered in this case study.
- 6. IEGPM: Independent Experts Group on Mobile Telephony. *Mobile Phones and Health: Section 1-Summary & Recommendations* (The Stewart Report), 2000. http://www.iegmp.org.uk/report/text.htm
 Excerpt (pg. 3) 1.18 There is now scientific evidence, however, which suggests that there may be biological effects occurring at exposures below these guidelines (paragraphs 5.176–5.194, 6.38). 1.19
 There are additional factors that need to be taken into account in assessing any possible health effects. Populations as a whole are not genetically homogeneous and people can vary in their susceptibility to environmental hazards. There are well-established examples in the literature of the genetic predisposition of some groups, which could influence sensitivity to disease. There could also be a dependence on age. We conclude therefore that it is not possible at present to say that exposure to RF radiation, even at levels below national guidelines, is totally without potential adverse health effects, and that the gaps in knowledge are sufficient to justify a precautionary approach.
- 7. Kheifets L, Repacholi M, Saunders R, van Deventer E. *The sensitivity of children to electromagnetic fields*. Pediatrics. 2005 Aug;116(2):e303-13. **Source** Department of Epidemiology, University of California School of Public Health, Los Angeles, California 90095-1772, USA. http://pediatrics.aappublications.org/content/116/2/e303.long **Excerpt (Pg. 310):** In today's world, technologic developments bring both social and economic benefits to large sections of society; however, the health consequences of these developments can be difficult to predict and manage. Nevertheless, even if the effects are small, a widespread exposure can have large public health consequences. When

risks are complex, an established cause-effect relationship is absent, or the scientific findings are not robustly quantifiable, the need for timely preventive action makes a precautionary approach an essential part of policy making. Many societies believe that this is particularly true regarding children (including the unborn child): they represent the future of the society, have the potential for longer exposure than adults, and yet are less able to manage their own risk. International guidance on occupational and public exposure to EMFs, described above, is based on avoiding risks to health that are well understood and for which there is good scientific evidence. However, with regard to childhood exposure to EMFs (and exposure during pregnancy), several factors argue for the adoption of precautionary measures, including the possibility that EMFs might affect children; the dread with which some of the diseases raised in this context, such as leukemia and brain cancer, are perceived; the involuntary nature of some of the exposure; its extensiveness; and its likely rapid growth in the future.

- 8. Leszczynski, D and Zhengping Xu. *Mobile phone radiation health risk controversy: the reliability and sufficiency of science behind the safety standards*. Health Res Policy Syst. 2010; 8: 2.2010 January 27. http://www.health-policy-systems.com/content/8/1/2 Partial Abstract: This indicates that the presently available scientific evidence is insufficient to prove reliability of the current safety standards. Therefore, we recommend to use precaution when dealing with mobile phones and, whenever possible and feasible, to limit body exposure to this radiation.
- 9. Marc Le Menestrel and Julian Rode, Why did business not react with precaution to early warnings?: Late lessons from early warnings: science, precaution, innovation Volume II, Part D.25. European Environment Agency, Report No. 1/2013, Copenhagen, Denmark, [Copy filed in Docket] Excerpt (pg. 35): The chapter shows how economic motives often drive non-precautionary business decisions. In virtually all reviewed cases it was perceived to be profitable for industries to continue using potentially harmful products or operations. However, decisions are also influenced by a complex mix of epistemological, regulatory, cultural and psychological aspects. For instance, characteristics of the research environment and the regulatory context can provide business actors with opportunities to enter into 'political actions' to deny or even suppress early warning signals. Also, business decision-makers face psychological barriers to awareness and acceptance of the conflicts of values and interests entailed by early warning signals.
- 10. Oberfeld G. A Rationale for a Biologically-based Public Exposure Standard for Electromagnetic Fields (ELF and RF) Section 22 Precaution in Action Global Public Health Advice Following BioInitiative 2007. BioInitiative Working Group, BioInitiative Report, 2012. [Copy filed in Docket] Excerpt (pg. 29): The European Parliament, the Council of Europe and various governmental agencies in Europe, Scandinavia, Israel, North America, India and Asia have called for better warnings, to reduce or eliminate exposures from wireless devices, to label devices with health warnings, to develop new, lower public safety standards, to protect sensitive subgroups (children, people who are sensitized to EMF and wireless radiation already (electrosensitivity), and to inform and protect pregnant women and their young from unnecessary exposures. The countries of France, Italy, Belgium, the Principality of Liechtenstein, Switzerland, Austria, the United Kingdom, and others have led in proposing new restrictions on wireless exposures, based on scientific and public health reviews of the evidence. The US Government Accountability Office has called for review of American (FCC) safety limits for wireless devices.
- 11. Yakymenko I, Sidorik E, Kyrylenko S, Chekhun V. *Long-term exposure to microwave radiation provokes cancer growth: evidences from radars and mobile communication systems*. Exp Oncol. 2011 Jun;33(2):62-70. http://www.ncbi.nlm.nih.gov/pubmed/21716201 [Copy available] **Abstract:** In this Review we discuss alarming epidemiological and experimental data on possible carcinogenic effects of

long term exposure to low intensity microwave (MW) radiation. Recently, a number of reports revealed that under certain conditions the irradiation by low intensity MW can substantially induce cancer progression in humans and in animal models. The carcinogenic effect of MW irradiation is typically manifested after long term (up to 10 years and more) exposure. Nevertheless, even a year of operation of a powerful base transmitting station for mobile communication reportedly resulted in a dramatic increase of cancer incidence among population living nearby. In addition, model studies in rodents unveiled a significant increase in carcinogenesis after 17-24 months of MW exposure both in tumorprone and intact animals. To that, such metabolic changes, as overproduction of reactive oxygen species, 8-hydroxi-2-deoxyguanosine formation, or ornithine decarboxylase activation under exposure to low intensity MW confirm a stress impact of this factor on living cells. We also address the issue of standards for assessment of biological effects of irradiation. It is now becoming increasingly evident that assessment of biological effects of non-ionizing radiation based on physical (thermal) approach used in recommendations of current regulatory bodies, including the International Commission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines, requires urgent reevaluation. We conclude that recent data strongly point to the need for re-elaboration of the current safety limits for non-ionizing radiation using recently obtained knowledge. We also emphasize that the everyday exposure of both occupational and general public to MW radiation should be regulated based on a precautionary principles which imply maximum restriction of excessive exposure.

- 12. Yakymenko I, Sidorik E. *Risks of carcinogenesis from electromagnetic radiation of mobile telephony devices.* Exp Oncol. 2010 Jul;32(2):54-60. http://www.ncbi.nlm.nih.gov/pubmed/20693976; Abstract: Among reproducible biological effects of low-intensive MWs are reactive oxygen species overproduction, heat shock proteins expression, DNA damages, apoptosis. The lack of generally accepted mechanism of biological effects of low-intensive non-ionizing radiation doesn't permit to disregard the obvious epidemiological and experimental data of its biological activity. Practical steps must be done for reasonable limitation of excessive EMR exposure, along with the implementation of new safety limits of mobile telephony devices radiation, and new technological decisions, which would take out the source of radiation from human brain.
- 13. Zinelis SA. The precautionary principle: radiofrequency exposures from mobile telephones and base stations. Environ Health Perspect. 2010 Jan;118(1):A16; author reply A16-7. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2831979/?tool=pubmed; [Full copy filed in Docket] **Abstract:** This study provides a defense against Dolan and Rowley (2009) criticism that the precautionary principle "is not appropriate to policy on the use of mobile telephones and the siting of base stations" because there is no established health hazard from the exposure to low-dose radiation.. " The past has taught us many lessons about risk from environmental exposures. For example, the lack of full scientific proof concerning the adverse effects of asbestos and the delay of precautionary action had devasting consequencies to human health [World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) 2005]. If asbestos had been banned in 1965, when the effects of asbestos on mesothelioma were plausible but unproven, the Netherlands alone would have saved approximately 52,000 victims and €30 billion for 1969–2030. An estimated 250,000–400,000 deaths from mesothelioma, lung cancer, and asbestosis caused by past asbestos exposure will occur the next 35 years in the European Union (COMEST 2005). In conclusion, concerning the exposure to electromagnetic fields, the precautionary principle should be applied to protect humans from environmental effects of non-thermal mechanisms

1B Peer reviewed published articles by reputable sources and government agencies on the use of the Precautionary Principal in Public Policy to protect public health:

- 1. American Public Health Association. *The precautionary principle and children's health*. Am J Public Health. 2001 Mar;91(3):495-6. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1446561/pdf/11236434.pdf [Copy to be filed in Docket] Excerpt (pg 495-496): The American Public Health Association, Recognizing that, for centuries, the cornerstone of public health policy and practice has been the prevention of injury and disease; and Recognizing that the US has signed the Rio Declaration on Environment and Development which states; In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation, a statement known as the Precautionary Principal; and Recognizing that the American Public Health Association has previously encouraged the implementation of the Precautionary Principle with regard to workplace chemical exposure prevention policies;...4 and Recognizing that many of these enterprises, projects, technologies, products, and substances are considered safe until proven harmful; and Recognizing that public health decisions must often be made in the absence of scientific certainty, or in the absence of perfect information; and Recognizing that some industries engaged in the production, release, or distribution of potentially hazardous products and processes use their influence to delay preventive action, arguing that the immediate expense of redesign to achieve pollution prevention is unwarranted, lacking scientific certainty about harmful health effects;5 and Recognizing that fetuses, children, and all developing organisms are often more susceptible to environmental contaminants than adults, and that agency policies and decisions often fail to reflect this unique susceptibility; 6 and Recognizing that proof of cause and effect relationships is often difficult to establish because of non-specificity of health effects, long latent periods, subtle changes in function that are difficult to detect without resource-intensive studies, and complex interactions of variables that contribute to adverse health effects;7 and Recognizing that Presidential Executive Order #13045 requires that all federal agencies, when developing policies, must explicitly consider their impacts on children, therefore, • Reaffirms its explicit endorsement of the precautionary principle as a cornerstone of preventive public health policy and practice, both in the U.S. and throughout the world; • Encourages governments at all levels, the private sector, and health professionals to promote and abide by this principle in order to protect the health and well-being of all developing children...Encourages precautionary action to prevent potential harm to reproductive health, infants, and children, even if some cause and effect relationships have not been established with scientific certainty;
- 2. Council of Europe, Standing Committee, Parliamentary Assembly (2011). Resolution 1815. The potential dangers of electromagnetic fields and their effect on the environment. Link accessed October 14 2012: http://assembly.coe.int/mainf.asp?link=/documents/adoptedtext/ta11/eres1815.htm (Excerpt at: 8.3.1.) develop within different ministries (education, environment and health) targeted information campaigns aimed at teachers, parents and children to alert them to the specific risks of early, ill-considered and prolonged use of mobiles and other devices emitting microwaves; 8.3.2. for children in general, and particularly in schools and classrooms, give preference to wired Internet connections, and strictly regulate the use of mobile phones by schoolchildren on school premises.
- 3. Cogliano, VJ. *The IARC Monographs: a resource for precaution and prevention.* Occup Environ Med. 2007 September; 64(9): 572. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2092573/ Source: International Agency for Research on Cancer, Lyon, France; **Abstract:** In an excellent discussion, Marco Martuzzi describes the precautionary principle as meaning that scientific uncertainty must not be

used as a reason to delay taking action. Deeply rooted in the history of public and environmental health, the precautionary principle has been embraced by ministers of health and environment across Europe. Martuzzi asserts that precaution is especially needed in areas fraught with complexity and uncertainty, for threats that may be irreversible or felt across generations, or when technological or societal change outpaces the accumulation of data... There are also inherent limitations to what epidemiology is able to study. For example, it is often difficult to attribute causality to a single factor, epidemiology cannot rule out a cancer hazard until more than 20 years of exposure have occurred, and it cannot rule out a 1-in-10 000 risk unless tens of thousands of people have been exposed...

- 4. European Environment Agency, (2001). Late lessons from early warnings: The precautionary principle 1896-2000, Volume I, Section 16 - Twelve Late Lessons. Environmental Issue Report No 22. EEA ,Copenhagen [Full copy filed in Docket] http://www.eea.europa.eu/publications/environmental_issue_report_2001_22; Excerpt: Box 16.1 (pg. **168).** Risk, uncertainty and ignorance: The precautionary principle is seen principally as away to deal with a lack of scientific certainty. A basic foundation for our conclusions concerns the nature of scientific certainty itself. There is an urgent need for a more complete and systematic basis for thinking about the different ways in which scientific uncertainty may pervade regulatory appraisal. First there is the familiar condition of risk, as formally defined in probability theory. This is where all possible outcomes are known in advance and where their relative likelihood can be adequately expressed as probabilities. Where this condition prevails, risk assessment is a valid technique that can save lives, prevent damage to the environment and provide a robust basis for decision-making. Still, the judgments over what is defined as at risk, and over the right balance to strike in decision-making, are necessarily laden with subjective assumptions and values. Under the condition of uncertainty, as formally defined, the adequate empirical or theoretical basis for assigning probabilities to outcomes does not exist. This may be because of the novelty of the activities concerned, or because of complexity or variability in their contexts. Either way, conventional risk assessment is too narrow in scope to be adequate for application under conditions of uncertainty. Although techniques such as safety factors, scenario or sensitivity analysis can be useful, they do not provide a way adequately to assess the impacts of different options. Here, more than ever, judgments about the right balance to strike in decision-making are laden with subjective assumptions and values... Once it is acknowledged that the likelihood of certain outcomes may not be fully quantifiable, or where certain other possibilities may remain entirely unaddressed, then uncertainty and ignorance, rather than mere risk characterize the situation.
- 5. European Environment Agency, (2013) Late lessons from early warnings: science, precaution, innovation, Volume II. Environmental issue report No. 1/2013 [Copy filed in Docket] http://www.eea.europa.eu/publications/late-lessons-2 Excerpt (pg 38): The first volume of Late Lessons, published in 2001, was a ground breaking report detailing the history of technologies subsequently found to be harmful. The new 750-page volume includes 20 new case studies, with farreaching implications for policy, science and society... The report also considers the warning signs emerging from technologies currently in use, including mobile phones, genetically modified organisms and nanotechnology. The historical case studies show that warnings were ignored or sidelined until damage to health and the environment was inevitable. In some instances, companies put short-term profits ahead of public safety, either hiding or ignoring the evidence of risk. In others, scientists downplayed risks, sometimes under pressure from vested interests. Such lessons could help avoid harm from emerging technologies...The world has changed since the first volume of Late Lessons was published. Technologies are now taken up more quickly than before, and are often rapidly adopted around the world. This means risks may spread faster and further, the report says, outstripping society's capacity to understand, recognize and respond to these effects in time to avoid harm. The report recommends the wider use of the 'precautionary principle' to reduce hazards in cases of new and largely untested technologies and chemicals. It states that scientific uncertainty is not a justification for inaction,

when there is plausible evidence of potentially serious harm. Key recommendations: Science should acknowledge the complexity of biological and environmental systems, particularly where there may be multiple causes of many different effects, the report says. It is increasingly difficult to isolate a single agent and prove beyond doubt that it causes harm. A more holistic view taking many different disciplines into account would also improve the understanding and prevention of potential hazards. Policy makers should respond to early warnings more rapidly, the report says, particularly in cases of large scale emerging technologies. It proposes that those causing any future harm should pay for the damage. Risk assessment can also be improved, the report says, by embracing uncertainty more broadly and acknowledging what is not known. For example, 'No evidence of harm' has often been often misinterpreted to mean 'evidence of no harm' when the relevant research was not available. The report calls for new forms of governance involving citizens in choices about innovation pathways and risk analysis. This would help to reduce exposure to hazards and encourage innovations with broader societal benefits. Greater interaction between business, governments and citizens could foster more robust and diverse innovations at less cost to health and the environment.

- 6. European Environmental Agency, Statement on Mobile Phones and the Potential Head cancer risk for the EMF Hearing on EMF, Council of Europe, Paris, February 25th 2011. Professor Jacqueline McGlade, Director, European Environment Agency, and David Gee, Senior Adviser, Science, Policy and Emerging issues. Link accessed October 29 2012: http://www.icems.eu/docs/StatementbyJMGFeb252011.pdf?f=/c/a/2009/12/15/MNHJ1B49KH.DTL
 Excerpt (pg. 2) The EU Commission and the EEA sees the precautionary principle as central to public policymaking where there is scientific uncertainty and high health, environmental and economic costs in acting, or not acting, when faced with conflicting evidence of potentially serious harm.
- 7. Gee D. *Late Lessons from Early Warnings: Towards realism and precaution with EMF?*Pathophysiology. 2009 Aug;16(2-3):217-31. Source: European Environment Agency, Kongens Nytorv 6, DK-1050 Copenhagen K, Denmark. http://www.ncbi.nlm.nih.gov/pubmed/19467848 [Copy filed in Docket] Abstract: The histories of some well-known public and environmental hazards, from the first scientifically based early warnings about potential harm, to the subsequent precautionary and preventive measures, have been reviewed by the European Environment Agency in their report "Late Lessons from Early Warnings: The Precautionary Principle 1896-2000". This paper summarizes some of the definitional and other issues that arise from the report and subsequent debates, such as the contingent nature of knowledge; the definitions of precaution, prevention, risk, uncertainty, and ignorance; the use of different strengths of evidence for different purposes; the nature and main direction of the methodological and cultural biases within the environmental health sciences; the need for transparency in evaluating risks; and public participation in risk analysis. These issues are relevant to the risk assessment of electro-magnetic fields (EMF). Some implications of these issues and of the "late lessons" for the evaluation and reduction of risks from EMF are indicated.
- 8. Gee D. A Rationale for a Biologically-based Public Exposure Standard for Electromagnetic Fields (ELF and RF) Section 23 The Precautionary Principal 2012 Supplement). BioInitiative Working Group, BioInitiative Report, 2012. http://www.bioinitiative.org/report/wp-content/uploads/pdfs/sec23 2012 The Precautionary Principle.pdf Excerpt (pg. 5): The IARC, and the EEA, may be wrong to suggest there could be a brain tumour risk from the extensive use of mobile phones, and we dearly hope we are wrong. However, it is worth noting that during over 30 years of classifying cancer risks, covering around 900 agents, IARC very rarely downgrades its judgments: in most cases tentative carcinogens become more certain carcinogens as time since first exposures and further research accumulates. Is it not worth gambling that mobile phones will be one of those very rare cases where IARC has over-classified an agent? We think not. The human cost of getting such

- a gamble wrong would be too great, especially in light of the relatively low cost of reducing exposures significantly.
- 9. Gee D. *More or less precaution? In Late lessons from early warnings: science, precaution, innovation Volume II, Part E.27.* European Environment Agency Report No. 1/2013, Copenhagen, Denmark [Copy filed in Docket] Excerpt (pg. 37): Despite its presence in a growing body of EU and national legislation and case law, the application of the precautionary principle has been strongly opposed by vested interests who perceive short term economic costs from its use. There is also intellectual resistance from scientists who fail to acknowledge that scientific ignorance and uncertainty, are excessively attached to conventional scientific paradigms, and who wait for very high strengths of evidence before accepting causal links between exposure to stressors and harm. The chapter focuses on some of the key issues that are relevant to a more common understanding of the precautionary principle and to its wider application. These include different and confusing definitions of the precautionary principle and of related concepts such as prevention, risk, uncertainty, variability and ignorance; common myths about the meaning of the precautionary principle; different approaches to the handling of scientific complexity and uncertainty; and the use of different strengths of evidence for different purposes.
- 10. Goldstein BD. *The precautionary principle and scientific research are not antithetical*. Environ. Health Perspect. 1999;107:A594–A595. [PubMed] Goldstein is with the University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1566805/pdf/envhper00517-0010.pdf Abstract: The essence of the Precautionary Principle is that society should not wait until it knows all of the answers before attempting to protect against significant harm. ... There will be times when society acts on the Precautionary Principle that it will not be possible to rapidly ascertain whether the action has been warranted or effective, for example, because of inadequate power for any feasible epidemiology study... Our society should be very willing to invoke the Precautionary Principle to protect public health and the environment, particularly when the scientific uncertainty includes a potentially disastrous worst-case scenario. However, simply stated, the more precautionary we are, the more often we will have acted unnecessarily. Responsible precaution requires that we accompany proposals for precautionary actions with a research agenda to decide if the actions, once taken, are justified.
- 11. Goldstein B D. *The precautionary principle also applies to public health actions*. Am J Public Health 2001. 911358–1361.1361. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1446778/ Bernard D. Goldstein is with the University Of Pittsburgh Graduate School Of Public Health, Pittsburgh, PA. Abstract: The precautionary principle asserts that the burden of proof for potentially harmful actions by industry or government rests on the assurance of safety and that when there are threats of serious damage, scientific uncertainty must be resolved in favor of prevention... Excerpt (Parag. 3): Public health advocates around the world have increasingly invoked the precautionary principle as a basis for preventive actions The upsurge in use of the term "precautionary principle" has been relatively sudden. For example, changes in the approach to hazardous air pollutants in the 1990 US Clean Air Act Amendments embody the precautionary principle. Until then, control of individual air pollutants in this category depended on a risk-based approach in which the burden of proof was on the US Environmental Protection Agency (EPA) to demonstrate that environmental levels of the air pollutant were likely to produce adverse effects. Further, the extent of imposed control measures was based on the feasibility of reducing risk. Instead, the 1990 amendments state that maximal available control technology is to be used on each of more than 180 pollutants unless the pollutant can be clearly shown to be harmless ... At its core, the precautionary principle contains many of the attributes of good public health practice, including a focus on primary prevention and a recognition that unforeseen and unwanted consequences of human activities are not unusual.

- 12. Grandjean P. *Implications of the precautionary principle for primary prevention and research*. Annu Rev Public Health. 2004;25:199–223. [PubMed] [Complete copy available]: **Abstract:** The precautionary principle (PP) is an extension of the public health presage that prevention is better than cure. **The PP has recently achieved new relevance in regard to serious but uncertain threats to human health and the environment and has now entered national and international legislation.** However, frameworks for its unambiguous application in practice are yet to be designed. They will depend on legal and cultural circumstances and are likely to involve pluralities of perspectives and stakeholder participation. The rules for causal reasoning and dose dependence need to be addressed and may be conveniently expressed in accordance with probability theory. Although the PP will allow action before convincing evidence is secured, it is not science averse. However, it provides an occasion to review environmental health research strategies, methodologies, and research-reporting traditions. From this perspective, current research is afflicted by important biases and insufficient focus on major environmental health problems.
- 13. Grandjean P, Bailar JC, Gee D, Needleman HL, Ozonoff DM, Richter E, Sofritti M, Soskolne CL. *Implications of the Precautionary Principle in research and policy making*. Am J Ind Med 2004. 45382–385.385. [PubMed] [Complete copy available]: Source: Institute of Public Health, University of Southern Denmark, Odense C, Denmark. Full copy to be filed in Abstract: The Precautionary Principle (PP) has recently been formally introduced into national and international law. The key element is the justification for acting in the face of uncertainty. The PP is thereby a tool for avoiding possible future harm associated with suspected, but not conclusive, environmental risks. Under the PP, the burden of proof is shifted from demonstrating the presence of risk to demonstrate its safety rather than the responsibility of public authorities to show harm. Past experiences show the costly consequences of disregarding early warnings about environmental hazards. Today, the need for applying the PP is even greater...
- 14. Grandjean P. Seven deadly sins of environmental epidemiology and the virtues of precaution.

 Epidemiology. 2008 Jan;19(1):158-62. Source: Department of Environmental Medicine, University of Southern Denmark, Odense, Denmark. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2639782/
 Abstract: The potentials for error in planning, conducting, reporting, and utilizing epidemiologic results can be considered in terms of the traditional 7 deadly sins. To counter these sins, epidemiologic virtues should be inspired by the precautionary principle. The remedies emphasize acknowledgment and exploration of the impact of uncertainties, weight-of-the-evidence assessments that consider what could be known given the opportunities for research, and epidemiologic strategies that facilitate the use of tentative, though innovative, studies in decision-making.
- 15. Hayes AW. *The precautionary principle*. Arh Hig Rada Toksikol. 2005 Jun;56(2):161-6.Source: Department of Environmental Health, Harvard School of Public Health, Boston, MA 01810, USA. http://www.ncbi.nlm.nih.gov/pubmed/15968832 Abstract: The Precautionary Principle in its simplest form states: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically". This Principle is the basis for European environmental law, and plays an increasing role in developing environmental health policies as well. It also is used in environmental decision-making in Canada and in several European countries, especially in Denmark, Sweden, and Germany. The Precautionary Principle has been used in the environmental decision-making process and in regulating drugs and other consumer products in the United States... Public participation is encouraged in both the review process and the decision-making process...

- 16. Hughes J. *How not to criticize the precautionary principle*. J Med Philos. 2006 Oct;31(5):447- 4. Source Keele University, Staffordshire, United Kingdom. http://www.ncbi.nlm.nih.gov/pubmed/17079207
- 17. Jamieson D, Wartenburg D. *The precautionary principle and electric and magnetic fields*. Am J Public Health 2001;91:1355–1358. [PMC free article] [PubMed] Abstract: Current environmental regulation represents a paternalistic policy, more concerned to avoid false postives than false negatives, limiting opportunities for individuals to make choices between risk-avoidance and risk-taking alternatives. For example, many exposures to magnetic fields could be reduced at little or no cost but are not considered seriously, owing to the uncertainty of risk and the concern to avoid false positives. Even though precautionary approaches that focus on avoiding false negatives often do not lead to adverse economic consequences or irrational choices, such approaches usually are not taken. The value of autonomy and the proper role of governmental paternalism with respect to environmental policy need to be considered more carefully in environmental decision making.
- 18. Jarosinska D, Gee D. *Children's environmental health and the precautionary principle*. International Journal of Hygiene and Environmental Health 210 (2007) 541–546: European Environment Agency, Kongens Nytorv 6, 1050 Copenhagen, Denmark: http://dx.doi.org/10.1016/j.ijheh.2007.07.017 [Copy filed in Docket] Excerpt (pg 543): "Primum non nocere' first do no harm. These words from Hippocrates' oath are one of the foundations of medical practice. When physicians face choices between uncertain benefits and possible harm, they must err on the side of safety, taking also into account the severity of the disease. Given the complex nature and uncertainty of environmental risks to children's health, the precautionary approach is necessary to identify and effectively prevent such risks, characterize uncertainties, and stimulate research and development of preventive alternatives. Children are more vulnerable to environmental stressors than adults, and have less control over their environment.
- 19. Kriebel D, Tickner J. Reenergizing public health through precaution. Am J Public Health 2001;91:1351–1355. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1446776/ [Complete article available] Abstract: The precautionary principle has provoked a spirited debate among environmentalists worldwide, but it is equally relevant to public health and shares much with primary prevention. Its central components are (1) taking preventive action in the face of uncertainty; (2) shifting the burden of proof to the proponents of an activity; (3) exploring a wide range of alternatives to possibly harmful actions; and (4) increasing public participation in decision making. Precaution is relevant to public health, because it can help to prevent unintended consequences of well-intentioned public health interventions by ensuring a more thorough assessment of the problems and proposed solutions. It can also be a positive force for change. Three aspects are stressed: promoting the search for safer technologies, encouraging greater democracy and openness in public health policy, and stimulating reevaluation of the methods of public health science.
- 20. Krimsky S. *The weight of scientific evidence in policy and law*. Am.J. Public Health 95 (2005) S129—S136. The author is with the Department of Urban and Environmental Policy and Planning at Tufts University. http://www.tufts.edu/~skrimsky/PDF/AJPH_WOE.PDF Excerpt (pg. 13) Studies that have measured the variance in expert judgments on the use of WOE in evaluating a hypothesis demonstrate that the application of WOE is not strictly a science but depends on the experience, as well as other tacit factors associated with the expert, such as their familiarity with or financial connection to the substance being evaluated. Experts who apply a WOE analysis to evaluate the human health hazards of a substance draw from their personal knowledge of similar compounds; situate the properties of the compound in a

ranking system; and, based on the diversity and quality of the evidence, reach an informed, albeit subjective, judgment on whether the likelihood that the substance is the cause of a human disease is strong, moderate, or weak (e.g., the substance is a human carcinogen, a reproductive toxicant, or an endocrine disruptor). Without an accepted canonical methodology or standard of weighing and combining information streams, and because subjective factors inevitably shape the outcome of the process, judges may not be in any better position than jurors to decide which WOE analysis used by expert witnesses is more credible or reliable. Excerpt (pg. 14) Writing about the environmental etiology of childhood diseases, Debaun and urney highlight the essential role of a conceptual framework for weighing the evidence. "Informed recommendations require systematic assessments of the weight of evidence from vailable studies and placement of the studies into a conceptual framework that allows for available data to be reviewed in the context of epidemiology principles of causal inference." Presuppositions within these frameworks about the value of different forms of evidence may bias the outcome of a WOE analysis. For example, some WOE approaches give higher weight to mechanistic information over epidemiological data. Where mechanistic knowledge may be unavailable for a particular substance, the value of excellent human epidemiological data may be reduced in the weighing schema because of *a priori* assumptions about evidence.

- 21. Martuzzi M. The precautionary principle: in action for public health. Occup Environ Med. 2007 September;64(9): 569–570. doi: 10.1136/oem.2006.030601 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2092570/; Excerpt (Parag. 1): Ministers of health, together with ministers of environment of the Member States in the World Health Organization (WHO) European Region (52 of them in 2004) declared: We reaffirm the importance of the precautionary principle as a risk management tool, and we therefore recommend that it should be applied. (Excerpt, Parag. 3) Caution may be common sense, but such common sense seems to be badly needed, and in big supply, at times when we are faced with increasing complexity and uncertainty, when potential health threats can be far-reaching and irreversible; when technological development and societal organization evolve fast enough to outpace, in numerous cases, the accumulation of data, knowledge and evidence; when the adverse consequences of policies may be felt at great distances, or by future generations. (Excerpt, Parag.6) For a start, the assumptions and limitations of science must be realized and made explicit. For example, epidemiological enquiry following the Popperian scheme of hypothesis generation and testing typically has high specificity and low sensitivity—that is, false positives are penalized more heavily than false negatives (Grandjean, 2004). As taught in textbooks, the recurrent snags of epidemiological studies, such as measurement error, exposure misclassification and many forms of bias, push risk estimates towards the null more often that the other way around.
- 22. Martuzzi M, Tickner J A. eds. *The precautionary principle: protecting public health, the environment and the future of our children* Copenhagen: WHO, 2004. http://www.euro.who.int/document/e83079.pdf Excerpt (Pg. 8): Currently available methods for evaluating the risks to human health and ecosystems, mostly designed to deal with direct associations between exposure and disease, are often not sufficient for effectively characterizing complex environmental risks. Limitations in scientific tools and in the ability to identify or to quantify causal relationships are occasionally misinterpreted as evidence of safety. Thus, when proposed or ongoing technologies or activities entail potential long-term, unknown adverse health effects, the need for more accurate scientific information has often been used as a reason for inaction.

- 23. Ricci PF, Cox LA Jr, MacDonald TR. Precautionary principles: a jurisdiction-free framework for decision-making under risk. Hum Exp Toxicol. 2004 Dec;23(12):579-600. http://www.ncbi.nlm.nih.gov/pubmed/15688986 Abstract: Fundamental principles of precaution are legal maxims that ask for preventive actions, perhaps as contingent interim measures while relevant information about causality and harm remains unavailable, to minimize the societal impact of potentially severe or irreversible outcomes. Such principles do not explain how to make choices or how to identify what is protective when incomplete and inconsistent scientific evidence of causation characterizes the potential hazards. Rather, they entrust lower jurisdictions, such as agencies or authorities, to make current decisions while recognizing that future information can contradict the scientific basis that supported the initial decision. After reviewing and synthesizing national and international legal aspects of precautionary principles, this paper addresses the key question: How can society manage potentially severe, irreversible or serious environmental outcomes when variability, uncertainty, and limited causal knowledge characterize their decision-making? Among the ethical basic attitudes, for those who operate this kind of studies, a particular value should be given to a precautionary attitude, and to the reference to the precautionary principle. The value of this principle in risk evaluation is internationally recognized and it has been considered as a guiding principle in different international Conferences and Guidelines (the universal recognition of the precautionary principle is reached in the 1992 UN Conference in Rio de Janeiro on Environment and Development. See also: The Cartagena Protocol on Bio safety in 2000. The 2001 Stockholm Convention on Persistent Organic Pollutants (POPs). The London Convention of 2001 on anti-fouling paints) [9, 10].
- 24. Tallacchini M. *Before and beyond the precautionary principle: epistemology of uncertainty in science and law.* Toxicol Appl Pharmacol. 2005 Sep 1;207(2 Suppl):645-51. Review. http://www.ncbi.nlm.nih.gov/pubmed/16054183 [Full copy available] Abstract: The precautionary principle has become, in European regulation of science and technology, a general principle for the protection of the health of human beings, animals, plants, and the environment. It requires that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". By focusing on situations of scientific uncertainty where data are lacking, insufficient, or inconclusive, the principle introduced a shift from a neutral legal attitude towards science to a bias in favor of safety, and a shift from the paradigm of science certain and objective to the awareness that the legal regulation of science involves decisions about values and interests... In democratic society, science may still have a special authoritative voice, but it cannot be the ultimate word on decisions that only the broader society may make.
- 25. Thomas JC, MPH, PhD, Sage M, MPH, Dillenberg J, DDS, MPH, and Guillory JV, DO, MPH. A Code of Ethics for Public Health. Am J Public Health. 2002 July; 92(7): 1057–1059. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447186/ Excerpt (pargh. 11): Principles of the Ethical Practice of Public Health
 - 1. Public health should address principally the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes.
 - 2. Public health should achieve community health in a way that respects the rights of individuals in the community.
 - 3. Public health policies, programs, and priorities should be developed and evaluated through processes that ensure an opportunity for input from community members.
 - 4. Public health should advocate for, or work for the empowerment of, disenfranchised community members, ensuring that the basic resources and conditions necessary for health are accessible to all people in the community.

- 5. Public health should seek the information needed to implement effective policies and programs that protect and promote health.
- 6. Public health institutions should provide communities with the information they have that is needed for decisions on policies or programs and should obtain the community's consent for their implementation.
- 7. Public health institutions should act in a timely manner on the information they have within the resources and the mandate given to them by the public.
- 8. Public health programs and policies should incorporate a variety of approaches that anticipate and respect diverse values, beliefs, and cultures in the community.
- 9. Public health programs and policies should be implemented in a manner that most enhances the physical and social environment.
- 10. Public health institutions should protect the confidentiality of information that can bring harm to an individual or community if made public. Exceptions must be justified on the basis of the high likelihood of significant harm to the individual or others.
- 11. Public health institutions should ensure the professional competence of their employees.
- 12. Public health institutions and their employees should engage in collaborations and affiliations in ways that build the public's trust and the institution's effectiveness.
- 26. World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) *The Precautionary Principle*. 2005. http://unesdoc.unesco.org/images/0013/001395/139578e.pdf. Excerpt (pg. 32): In summary, the PP applies when the following conditions are met: there exist considerable scientific uncertainties; there exist scenarios (or models) of possible harm that are scientifically reasonable (that is based on some scientifically plausible reasoning); uncertainties cannot be reduced in the short term without at the same time increasing ignorance of other relevant factors by higher levels of abstraction and idealization; the potential harm is sufficiently serious or even irreversible for present or future generations or otherwise morally unacceptable; there is a need to act now, since effective counteraction later will be made significantly more difficult or costly at any later time.
- 27. World Health Organization Regional Office for Europe. *Declaration: fourth Ministerial Conference on Environment and Health*, Budapest, Hungary, 23–25 June 2004. Copenhagen: WHO, 2004, http://www.euro.who.int/document/e83335.pdf Excerpt (pg 6): We recognize the fundamental value, in the context of environmental policy-making, of the Rio Declaration on Environment and Development of 1992, which says that "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" and of the European Commission's 2000 Communication on the Precautionary Principle (COM(2000)1 final). We reaffirm the importance of the precautionary principle as a risk management tool, and we therefore recommend that it should be applied where the possibility of serious or irreversible damage to health or the environment has been identified and where scientific evaluation, based on available data, proves inconclusive for assessing the existence of risk and its level but is deemed to be sufficient to warrant passing from inactivity to policy alternatives. 17b. We welcome the work done in WHO on the precautionary principle and more generally on precautionary considerations. We acknowledge the WHO document Dealing with uncertainty how can the precautionary principle help protect the future of our children?
- 28. World Health Organization Regional Office for Europe. The precautionary principle: protecting public health, the environment and the future of our children; Dealing with uncertainty how can the precautionary principle help protect the future of our children? Copenhagen: WHO, 2004, http://www.euro.who.int/document/e83079.pdf Excerpt (pg 16): In line with the mandate given by the WHO Third Ministerial Conference on Environment and Health, protecting children and future

generations from environmental impacts should be a priority...Pursuant to that mandate, this document is the first to develop an approach that will promote and encourage protective public health measures in areas of emerging concern about environmental impacts on children's health, based on the precautionary principle. It focuses on how the precautionary principle can be applied to the protection of children's health. (Excerpt, pg. 17) The goal of this document is to orient and improve environment and health decisions designed to protect children and future generations under conditions of uncertainty and complexity, while stimulating more sustainable forms of development. It presents a decision making approach to the precautionary principle that is sufficiently flexible to be applied by all countries in WHO's European Region, regardless of their available resources. (Excerpt, pg. 25) The steps in such an approach for applying precaution to the health of children and future generations include... Excerpt (pg. 66): According to the principle, when there are credible threats of harm, precautionary action should be taken, even when full understanding of the effects of a proposed activity is lacking. In other words, the precautionary principle combines the ethical notion of duty to prevent harm with the realities of the limits of scientific understanding.

29. World Health Organization Regional Office for Europe. *Dealing with uncertainty: setting the agenda for the 5th Ministerial Conference on Environment and Health*, 2009. Report of a WHO meeting. Copenhagen, Denmark, 15–16 December 2005. Copenhagen: WHO, 2006, Available at http://www.euro.who.int/Document/HMS/uncertaintymtgrep.pdf (accessed June 2007)

1C The Precautionary Principal has recently (2008 to 2012) been applied to US public health policies, environmental policies, medical policies, and other industries:

- 1. Chaudry RV. *The Precautionary Principle, public health, and public health nursing.* Public Health Nurs. 2008 May-Jun;25(3):261-8. doi: 10.1111/j.1525-1446.2008.00703.x. Source: The Ohio State University College of Nursing, Columbus, Ohio 43210, USA. http://www.ncbi.nlm.nih.gov/pubmed/18477377 Abstract: The Precautionary Principle posits that, in the absence of certainty, the appropriate course of action is to err on the side of caution. The Principle has been applied to decision making and policy development related to environmental health issues both internationally and in the United States. The American Public Health Association and the American Nurses Association (ANA) have issued policy statements that invoke the Precautionary Principle, and the Principle has been incorporated into statements that describe the practice of public health nursing. Nursing has always recognized the relationship of the environment with the health of humans-individuals, families, populations, and communities (ANA). The increasing attention to the Precautionary Principle comes at a time of redefinition of the field of public health, environmental public health, and the practice of public health nursing. Thus, it is crucial that practicing public health nurses understand the Precautionary Principle and its relevance to the practice of public health, public health nursing, and the current and future health individuals, families, populations, and communities.
- 2. deFur PL, Kaszuba M. *Implementing the precautionary principle*. Sci Total Environ. 2002 Apr 8;288(1-2):155-65. **Source:** Center for Environmental Studies, Virginia Commonwealth University, Richmond 23284-3050, USA. http://www.ncbi.nlm.nih.gov/pubmed/12013543 **Abstract:** The precautionary principle can be found in international treaties that protect human health and the environment from a variety of pollutants and perturbations. One of the earliest forms of the precautionary principle was used in the 1980s in Europe to protect the North Sea. In 1992, the Rio

Declaration specifically included the precautionary principle in calling on nations to protect the environment. The US articulation that best embodies this approach to environment and human health protection is the *Wingspread statement: 'When an activity raises threats of harm to human health or the environment, precautionary measures should be taken, even if some cause and effect relationships are not fully established scientifically.'* The key element is the matter of acting in the face of uncertainty. Applications of the precautionary principle are not, however, new to US environmental policy and management. The present paper uses case studies to examine the application of the precautionary principle to environmental decisions. These cases range from ecosystem protection on the Charles River, Massachusetts, to the effort to prevent computer crashes at the end of the year 2000.

- 3. Germain M, Ghibu S, Delage G. *The precautionary principle in blood safety: not quite the same as aiming for zero risk.* Transfus Med Rev. 2012 Apr;26(2):181-4; reply pg 184-6. doi: 10.1016/j.tmrv.2011.10.003. Epub 2011 Dec 5. http://www.ncbi.nlm.nih.gov/pubmed/22153563
- 4. Guidotti TL. *Applying the precautionary principle*. Arch Environ Occupational Health. 2012;67(2):63-4; http://www.ncbi.nlm.nih.gov/pubmed/22524644
- 5. Krimsky S. *The precautionary approach*. Forum for Applied Research and Public Policy. 1999;13:34–37. http://www.tufts.edu/~skrimsky/PDF/precautionary.PDF Abstract: Research findings on the toxic effects of chemical endocrine disruptors on animals, including humans, suggest that a precautionary approach be taken for industrial chemicals and other environmental pollutants. The traditional principle that a higher dose of a particular chemical would have a greater impact cannot be relied on for endocrine disruptors. Thus, industries must first show that the chemicals they are introducing have no adverse effects before their products are to be allowed to be marketed.
- 6. Porteri C. *Genetics and psychiatry: a proposal for the application of the precautionary principle.* Med Health Care Philos. 2012 Mar 30. [Epub ahead of print] http://www.ncbi.nlm.nih.gov/pubmed/22460929
- 7. Warshaw J. *The Trend Towards Implementing the Precautionary Principle in US Regulation of Nanomaterials.* Dose Response. 2012; 10(3): 384–396.

 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3430399; Abstract: In comparison, balancing risks and benefits is more complex for emerging technologies such as nanotechnology because of the uncertainties presented when commercialization outpaces science's understanding of risk...The precautionary principle is one construct that can guide regulators in this situation. It is often stated as a single definitive statement, but is in fact a spectrum of approaches that is providing a framework for regulating nanotechnology. The precautionary principle guides its adherents to reject the assumptions that all substances are safe to use in the absence of a full characterization, and to formulate a regulatory standard that acknowledges uncertainty and mandates or encourages some minimum precautions in the face of it.
- 8. Wilson K. A framework for applying the precautionary principle to transfusion safety. Transfus Med Rev. 2011 Jul;25(3):177-83. Epub 2011 Mar 22. Abstract: The precautionary principle has become highly influential in the formation of policies concerning transfusion safety...This article provides a guide to applying precaution to matters of transfusion safety. Types of risk-based decision-making can be classified as strong, intermediate/weak, or no precaution by determining the strength of evidence required to apply a protective measure and the extent of the protective measure applied. The decision on what type of precaution to implement can then be determined based on the response to the following questions for a given transfusion safety matter: (1) Is the extent of the exposure large? (2) Is the consequence of the exposure serious? (3) Is the consequence of the exposure irreversible? (4) Is there minimal cost associated with the removal of the exposure? (5) Is there a minimal negative health effect

associated with removing the exposure? Using this approach can help standardize the approach to applying precaution in transfusion safety.

9. Weed DL, McKeown RE. *Science and social responsibility in public health*. Environ Health Perspect. 2003 Nov;111(14):1804-8. Source: Office of Preventive Oncology, Division of Cancer Prevention, National Cancer Institute, Rockville, Maryland 20852, USA. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1241728/